

**THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

ENDO PHARMACEUTICALS INC.,

Plaintiff,

v.

ROXANE LABORATORIES, INC.,

Defendant.

Case No. 13-CV-03288-TPG

PUBLICLY FILED
REDACTED VERSION

**ROXANE LABORATORIES, INC.'S AMENDED ANSWER, AFFIRMATIVE
DEFENSES AND COUNTERCLAIMS TO PLAINTIFF'S COMPLAINT**

Defendant Roxane Laboratories, Inc. ("Roxane") for its Answer, Affirmative Defenses, and Counterclaims to Plaintiff Endo Pharmaceuticals Inc.'s ("Endo") Complaint for Patent Infringement, states as follows:

PARTIES

1. Roxane is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 1 of the Complaint and, therefore, denies them.

2. Roxane admits that Roxane is a corporation organized and existing under the laws of the State of Nevada and has a principal place of business at 1809 Wilson Road, Columbus, Ohio 43228. Roxane denies all other allegations contained in paragraph 2 of the Complaint.

3. Roxane admits that Roxane is registered to do business in New York and maintains a registered agent in New York. Roxane denies all other allegations contained in paragraph 3 of the Complaint.

NATURE OF ACTION

4. Roxane admits that the Complaint purports to allege a civil action for patent infringement. Roxane also admits that the Complaint purports to allege an action seeking a Declaratory Judgment under 28 U.S.C. §§ 2201 and 2202. Roxane denies all other allegations contained in paragraph 4 of the Complaint.

JURISDICTION AND VENUE

5. Roxane denies the allegations contained in paragraph 5 of the Complaint.

6. For purposes of this action, Roxane consents that venue is proper in this district. Roxane denies all other allegations contained in paragraph 6 of the Complaint.

7. To the extent that paragraph 7 of the Complaint states conclusions of law, Roxane states that no response is required. Roxane denies all other allegations contained in paragraph 7 of the Complaint.

8. Roxane admits that it filed Abbreviated New Drug Application (“ANDA”) No. 200822 with the United States Food and Drug Administration (“FDA”), seeking approval to commercially market a generic version of OPANA[®] ER. Roxane denies all other allegations contained in paragraph 8 of the Complaint.

9. To the extent that paragraph 9 of the Complaint states conclusions of law, Roxane states that no response is required. Roxane denies all other allegations contained in paragraph 9 of the Complaint.

10. Roxane admits that it sells certain generic drug products in the Southern District of New York and denies all allegations contained in paragraph 10 of the Complaint.

11. To the extent that paragraph 11 of the Complaint states conclusions of law, Roxane states that no response is required. Roxane denies all other allegations contained in paragraph 11 of the Complaint.

12. To the extent that paragraph 12 of the Complaint states conclusions of law, Roxane states that no response is required. Roxane denies all other allegations contained in paragraph 12 of the Complaint.

FACTUAL BACKGROUND

13. Upon information and belief, Roxane admits that New Drug Application (“NDA”) No. 021610 was approved by the FDA and that Endo Pharmaceuticals is listed as the applicant for that NDA. Roxane denies all other allegations contained in paragraph 13 of the Complaint.

14. Upon information and belief, Roxane admits that NDA No. 201655 was submitted to the FDA. Roxane denies all other allegations contained in paragraph 14 of the Complaint.

15. Roxane is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 15 of the Complaint and, therefore, denies them.

16. Roxane is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 16 of the Complaint and, therefore, denies them.

17. Roxane is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 17 of the Complaint and, therefore, denies them.

ENDO’S PATENTS

18. Roxane admits that what purports to be a copy of U.S. Patent No. 7,851,482 (“482 patent”) is attached to the Complaint as Exhibit A. Roxane further admits that Exhibit A

is entitled “Method for Making Analgesics” and lists Johnson Matthey as assignee. Roxane further admits that the ‘482 patent lists Jen-Sen Dung, Erno M. Keskeny, and James J. Mencil as “Inventors.” Roxane denies all other allegations contained in paragraph 18 of the Complaint.

19. Roxane is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 19 of the Complaint and, therefore, denies them.

20. Roxane admits that what purports to be a copy of U.S. Patent No. 8,309,122 (“‘122 patent”) is attached to the Complaint as Exhibit B. Roxane further admits that Exhibit is entitled “Oxymorphone Controlled Release Formulations” and lists Endo Pharmaceuticals, Inc. as assignee. Roxane further admits that the ‘122 patent lists Huai-Hung Kao, Anand R. Baichwal, Troy McCall, and David Lee as “Inventors.” Roxane denies all other allegations contained in paragraph 20 of the Complaint.

21. Roxane is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 21 of the Complaint and, therefore, denies them.

22. Roxane admits that what purports to be a copy of U.S. Patent No. 8,329,216 (“‘216 patent”) is attached to the Complaint as Exhibit C. Roxane further admits that Exhibit is entitled “Oxymorphone Controlled Release Formulations” and lists Endo Pharmaceuticals, Inc. as assignees. Roxane further admits that the ‘216 patent lists Huai-Hung Kao, Anand R. Baichwal, Troy McCall, and David Lee as “Inventors.” Roxane denies all other allegations contained in paragraph 22 of the Complaint.

23. Roxane is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 23 of the Complaint and, therefore, denies them.

24. Roxane denies the allegations contained in paragraph 24 of the Complaint.

25. Roxane admits that the '482, '122 and '216 patents are listed in Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") with respect to NDA 201655. Roxane also admits that the Orange Book also lists U.S. Patent Nos. 8,114,383, 8,192,722 and 8,309,060 with respect to NDA 201655. Roxane denies all other allegations contained in paragraph 25 of the Complaint.

26. Roxane admits that it filed ANDA No. 200822. Roxane's ANDA speaks for itself as to the contents. Roxane denies all other allegations contained in paragraph 26 of the Complaint.

27. Roxane admits that it was a party in *Endo Pharmaceuticals Inc., et al., v. Roxane Laboratories, Inc.* in the United States District Court, District of New Jersey, Civil Action Nos. 10-cv-00534-KSH-PS and 10-cv-1964-KSH-PS. The documents related to those matters speak for themselves as to the contents. Roxane also admits that Endo and Roxane settled the infringement dispute and those cases were dismissed. Roxane denies all other allegations contained in paragraph 27 of the Complaint.

28. Roxane admits that pursuant to the parties' settlement agreement, Roxane was granted a license. The settlement agreement speaks for itself. Roxane denies all other allegations in paragraph 28 of the Complaint.

29. Roxane admits that ANDA 200822 seeks to request permission from the FDA to market and sell Roxane's Generic Oxymorphone ER Tablets described therein. Roxane denies all other allegations contained in paragraph 29 of the Complaint.

30. Roxane denies all the allegations contained in paragraph 30 of the Complaint.

31. Roxane denies all the allegations contained in paragraph 31 of the Complaint.

COUNT I

(INFRINGEMENT OF THE '482 PATENT)

32. Roxane repeats, reasserts, and incorporates by reference its answers to paragraphs 1-31 of the Complaint above, as if fully set forth herein.

33. Roxane denies all the allegations contained in paragraph 33 of the Complaint.

34. Roxane denies all the allegations contained in paragraph 34 of the Complaint.

35. Roxane denies all the allegations contained in paragraph 35 of the Complaint.

COUNT II

(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '482 PATENT)

36. Roxane repeats, reasserts, and incorporates by reference its answers to paragraphs 1-35 of the Complaint above, as if fully set forth herein.

37. Roxane admits that the Complaint purports to allege an action seeking a Declaratory Judgment under 28 U.S.C. §§ 2201 and 2202. Roxane denies all other allegations contained in paragraph 37 of the Complaint.

38. To the extent that paragraph 38 of the Complaint states conclusions of law, Roxane states that no response is required. Roxane denies all other allegations contained in paragraph 38 of the Complaint.

39. Roxane denies all allegations contained in paragraph 39 of the Complaint.

40. Roxane denies all allegations contained in paragraph 40 of the Complaint.

41. Roxane denies all allegations contained in paragraph 41 of the Complaint.

42. Roxane denies all allegations contained in paragraph 42 of the Complaint.

COUNT III

(INFRINGEMENT OF THE '122 PATENT)

43. Roxane repeats, reasserts, and incorporates by reference its answers to paragraphs 1-42 of the Complaint above, as if fully set forth herein.

44. Roxane denies all the allegations contained in paragraph 44 of the Complaint.

45. Roxane denies all the allegations contained in paragraph 45 of the Complaint.

46. Roxane denies all the allegations contained in paragraph 46 of the Complaint.

COUNT IV

(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '122 PATENT)

47. Roxane repeats, reasserts, and incorporates by reference its answers to paragraphs 1-46 of the Complaint above, as if fully set forth herein.

48. Roxane admits that the Complaint purports to allege an action seeking a Declaratory Judgment under 28 U.S.C. §§ 2201 and 2202. Roxane denies all other allegations contained in paragraph 48 of the Complaint.

49. To the extent that paragraph 49 of the Complaint states conclusions of law, Roxane states that no response is required. Roxane denies all other allegations contained in paragraph 49 of the Complaint.

50. Roxane denies all allegations contained in paragraph 50 of the Complaint.

51. Roxane denies all allegations contained in paragraph 51 of the Complaint.

52. Roxane denies all allegations contained in paragraph 52 of the Complaint.

53. Roxane denies all allegations contained in paragraph 53 of the Complaint.

COUNT V

(INFRINGEMENT OF THE '216 PATENT)

54. Roxane repeats, reasserts, and incorporates by reference its answers to paragraphs 1-53 of the Complaint above, as if fully set forth herein.

55. Roxane denies all the allegations contained in paragraph 55 of the Complaint.

56. Roxane denies all the allegations contained in paragraph 56 of the Complaint.

57. Roxane denies all the allegations contained in paragraph 57 of the Complaint.

COUNT VI

(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '216 PATENT)

58. Roxane repeats, reasserts, and incorporates by reference its answers to paragraphs 1-57 of the Complaint above, as if fully set forth herein.

59. Roxane admits that Complaint purports to allege an action seeking a Declaratory Judgment under 28 U.S.C. §§ 2201 and 2202. Roxane denies all other allegations contained in paragraph 59 of the Complaint.

60. To the extent that paragraph 49 of the Complaint states conclusions of law, Roxane states that no response is required. Roxane denies all other allegations contained in paragraph 60 of the Complaint.

61. Roxane denies all allegations contained in paragraph 61 of the Complaint.

62. Roxane denies all allegations contained in paragraph 62 of the Complaint.

63. Roxane denies all allegations contained in paragraph 63 of the Complaint.

64. Roxane denies all allegations contained in paragraph 64 of the Complaint.

PRAYER FOR RELIEF

Roxane specifically denies that Endo is entitled to the general or specific relief requested against Roxane, or to any relief whatsoever, and prays for judgment in favor of Roxane dismissing this action with prejudice, and awarding Roxane its reasonable attorneys' fees pursuant to 35 U.S.C. § 285, interest, and costs of this action, and such other or further relief as this Court may deem just and proper.

AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth in its Answer and without admitting any allegations of the Complaint not otherwise admitted, Roxane avers and asserts the following Affirmative Defenses to Endo's Complaint.

First Affirmative Defense **(Existence of a License to the '482 Patent)**

1. Plaintiff's claims are barred because Roxane was granted a license to the '482 Patent by Johnson Matthey Public Limited Company, the original assignee of the '482 patent before the '482 patent was, upon information and belief, assigned to Plaintiff.

Second Affirmative Defense **(Noninfringement of U.S. Patent No. 7,851,482)**

2. The manufacture, use, sale, offer to sell, or importation into the United States of Roxane's proposed oxymorphone hydrochloride products that are the subject of ANDA No. 200822 would not and will not directly, indirectly, contributorily, and/or by inducement, infringe any validly construed claim of U.S. Patent No. 7,851,482 ("the '482 patent") either literally or under the doctrine of equivalents.

Third Affirmative Defense **(Invalidity of U.S. Patent No. 7,851,482)**

3. Upon information and belief, the claims of the '482 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to, §§ 101, 102, 103, and/or 112.

Fourth Affirmative Defense **(Noninfringement of U.S. Patent No. 8,309,122)**

4. The manufacture, use, sale, offer to sell, or importation into the United States of Roxane's proposed oxymorphone hydrochloride products that are the subject of ANDA No.

200822 would not and will not directly, indirectly, contributorily, and/or by inducement, infringe any validly construed claim of U.S. Patent No. 8,309,122 (“the ‘122 patent”) either literally or under the doctrine of equivalents.

Fifth Affirmative Defense
(Invalidity of U.S. Patent No. 7,851,122)

5. Upon information and belief, the claims of the ‘122 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to, §§ 101, 102, 103, and/or 112.

Sixth Affirmative Defense
(Noninfringement of U.S. Patent No. 8,329,216)

6. The manufacture, use, sale, offer to sell, or importation into the United States of Roxane’s proposed oxymorphone hydrochloride products that are the subject of ANDA No. 200822 would not and will not directly, indirectly, contributorily, and/or by inducement, infringe any validly construed claim of U.S. Patent No. 8,329,216 (“the ‘216 patent”) either literally or under the doctrine of equivalents.

Seventh Affirmative Defense
(Invalidity of U.S. Patent No. 8,329,216)

7. Upon information and belief, the claims of the ‘216 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to, §§ 101, 102, 103, and/or 112.

Eighth Affirmative Defense
(Failure to state a claim upon which relief may be granted)

8. Plaintiffs’ Complaint fails to state a claim upon which relief may be granted.

Ninth Affirmative Defense
(Lack of Subject Matter Jurisdiction)

9. Plaintiff’s claims are barred for lack of subject matter jurisdiction.

Tenth Affirmative Defense
(Unclean Hands)

10. Endo has engaged in conduct during its negotiations with Roxane and the pendency of this litigation that, considered separately or together, constitute unclean hands. As a result, Endo should be precluded from any recovery in this suit.

11. Upon information and belief, Endo filed this lawsuit asserting U.S. Patent No. 7,851,482 (“the ‘482 patent”) against Roxane with knowledge that Roxane has a license, arising out of its supply agreement with Johnson Matthey, the former owner of the ‘482 patent, to purchase and sell the active pharmaceutical ingredient in Roxane’s generic version of the original formulation Opana® ER.

12. Upon information and belief, before Endo purchased the ‘482 patent from Johnson Matthey, [REDACTED]

[REDACTED]

[REDACTED]

13. Upon information and belief, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Upon information and belief, [REDACTED]

[REDACTED]

[REDACTED]

14. [REDACTED]

[REDACTED]

[REDACTED]

15. These actions by Endo are part of an improper effort to keep Roxane from entering the generic oxymorphone hydrochloride market through means beyond the legitimate rights that Endo owns under the patents.

16. By filing and maintaining this lawsuit in light of these actions, Endo is not coming to this Court with clean hands and therefore deserves no remedy from this Court.

COUNTERCLAIMS

1. Counterclaimant Roxane Laboratories, Inc. (“Roxane”) is a corporation organized under the laws of Nevada, having a principal place of business at 1809 Wilson Road, Columbus, Ohio 43228-8601.

2. Upon information and belief, Plaintiff and Counterclaim Defendant Endo Pharmaceuticals Inc. (“Endo”) is a Delaware corporation, having its principal place of business at 1400 Atwater Drive, Malvern, PA 19355.

3. Roxane holds Abbreviated New Drug Application (“ANDA”) No. 200822 with the United States Food and Drug Administration (“FDA”), seeking approval to commercially market a generic version of oxymorphone hydrochloride.

4. As a consequence of Plaintiff’s Complaint against Roxane, there is an existing, continuing, actual controversy between Endo and Roxane regarding the alleged infringement and validity of U.S. Patent No. 7,851,482 (“482 patent”), U.S. Patent No. 8,309,122 (“122 patent”) and U.S. Patent No. 8,329,216 (“216 patent”) (collectively, “the patents-in-suit”).

5. This Court has jurisdiction over the subject matter of these counterclaims pursuant to §§ 1331 and 1338(a) of Title 28 of the United States Code, as they involve claims arising out of the United States Patent Act, 35 U.S.C. § 1, *et seq.*

6. This Court may declare the rights and legal relations for the parties pursuant to 28 U.S.C. §§ 2201 and 2202 and 35 U.S.C. § 271(e)(5) because Roxane's Counterclaims present an actual controversy within the Court's jurisdiction.

7. Venue for these Counterclaims is proper in this District in which Plaintiff's complaint is pending.

COUNT 1

Declaratory Judgment of Noninfringement of the '482 Patent

8. The manufacture, use, sale, offer to sell, or importation into the United States of Roxane's proposed generic oxymorphone hydrochloride products that are subject of ANDA 200822 would not and will not directly, indirectly, contributorily, and/or by inducement, infringe any validly construed claim of the '482 patent either literally or under the doctrine of equivalents.

COUNT 2

Declaratory Judgment of Invalidity of the '482 Patent

9. The claims of the '482 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112.

COUNT 3

Declaratory Judgment of Noninfringement of the '122 Patent

10. The manufacture, use, sale, offer to sell, or importation into the United States of Roxane's proposed generic oxymorphone hydrochloride products that are subject of ANDA 200822 would not and will not directly, indirectly, contributorily, and/or by inducement, infringe

any validly construed claim of the '122 patent either literally or under the doctrine of equivalents.

COUNT 4

Declaratory Judgment of Invalidity of the '122 Patent

11. The claims of the '122 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112.

COUNT 5

Declaratory Judgment of Noninfringement of the '216 Patent

12. The manufacture, use, sale, offer to sell, or importation into the United States of Roxane's proposed generic oxymorphone hydrochloride products that are subject of ANDA 200822 would not and will not directly, indirectly, contributorily, and/or by inducement, infringe any validly construed claim of the '216 patent either literally or under the doctrine of equivalents.

COUNT 6

Declaratory Judgment of Invalidity of the '216 Patent

13. The claims of the '216 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112.

ROXANE'S PRAYER FOR RELIEF

WHEREFORE, Roxane respectfully requests that the Court enter judgment against Plaintiff as follows:

A. Declaring that Roxane would not and will not directly, indirectly, contributorily, and/or by inducement, infringe any validly construed claim of United States Patent No.

7,851,482, either literally or under the doctrine of equivalents;

B. Declaring that Roxane would not and will not directly, indirectly, contributorily, and/or by inducement, infringe any validly construed claim of United States Patent No.

8,309,122, either literally or under the doctrine of equivalents;

C. Declaring that Roxane would not and will not directly, indirectly, contributorily, and/or by inducement, infringe any validly construed claim of United States Patent No.

8,329,216, either literally or under the doctrine of equivalents;

D. Declaring that the patent claims in United States Patent No. 7,851,482 are invalid for failure to comply with one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112;

E. Declaring that the patent claims in United States Patent No. 8,309,122 are invalid for failure to comply with one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112;


F. Declaring that the patent claims in United States Patent No. 8,329,216 are invalid for failure to comply with one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112;

G. Declaring this case an exceptional case under 35 U.S.C. § 285 and awarding Roxane its reasonable costs and attorneys' fees incurred in connection with this action; and

H. Such further and other relief as this Court may deem just and proper.

Dated: November 21, 2014

Respectfully Submitted,

A handwritten signature in black ink, appearing to read 'PS', is written over a horizontal line.


Paul Sudentas
psudentas@lockelord.com
Alan B. Clement
aclement@lockelord.com
Locke Lord LLP
3 World Financial Center
New York, New York 10281
(212) 415 8600

Scott B. Feder
sfeder@lockelord.com
Myoka Kim Goodin
mkgoodin@lockelord.com
Amanda K. Kelly
akelly@lockelord.com
Wasim K. Bleibel
wbleibel@lockelord.com
Locke Lord LLP
111 South Wacker Drive
Chicago, Illinois 60622
(312) 443-0700

*Attorneys for Defendant
Roxane Laboratories, Inc.*

CERTIFICATE OF SERVICE

I hereby certify that, on November 21, 2014, I electronically filed the attached ROXANE LABORATORIES, INC.'S ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS TO PLAINTIFF'S COMPLAINT with the clerk of the Court by using the Court's ECF system, and accordingly served all parties who receive notice of the filing via the Court's ECF system and via email.



Paul Sudentas